UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

VIVIAN BRANCHOFSKY, on behalf of herself and all others similarly situated,	)	**No.**
Plaintiff,	)	
vs.	)	**CLASS-ACTION COMPLAINT**
BOEHRINGER INGELHEIM INT'L GMBH and BOEHRINGER INGELHEIM PHARM., INC.,	)	
Defendants.	)	*Electronically Filed*

End-Payor Plaintiff, Vivian Branchofsky, on behalf of herself and all others similarly situated, hereby seeks damages and equitable relief resulting from Defendants' violations of federal and Vermont statutory law and Vermont common law.

INTRODUCTION

1. Plaintiff brings these claims for damages based on Defendants' elaborate scheme to eliminate competition in order to preserve wrongfully and extend their monopoly power and monopoly profits on Mirapex.

2. Defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively "Boehringer" or "Defendants") have manufactured and sold the branded prescription drug Mirapex since 1997. Mirapex is indicated for Parkinson's disease and Restless Leg Syndrome, and its active pharmaceutical ingredient is pramipexole dihydrochloride. Boehringer has reaped monopoly profits on Mirapex from 1997 to the present time.

3. Three generic drug manufacturers, Barr Pharmaceuticals, Inc. ("Barr"), Mylan Pharmaceuticals, Inc. ("Mylan") and Alembic Limited ("Alembix), each developed a generic

version of Mirapex to sell in competition with Defendants Boehringer. In their applications to the Food and Drug Administration, these three manufacturers asserted that their products were bioequivalent to Mirapex and did not infringe on any valid patent owned or licensed by Defendants. Because of Defendants' actions, however, no generic formulation of Mirapex has been made available to the market.

4. To preserve their monopoly position, Defendants raised barriers and unlawfully prevented competition from generic drugs that would have lowered prices to end payors including, but not limited to, the following:

(a) obtaining U.S. Patent No. 4,886,812 (-812 Patent"), which it knew or should have known was invalid because the patent claimed the same compound for which Boehringer had already received patent protection in U.S. Patent No. 4,843,086 (-086 Patent");

(b) listing the '812 Patent in the Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") to raise entry barriers;

(c) knowingly seeking a five-year extension of the invalid '812 Patent;

(d) suing both Barr and Mylan in the United States District Court for the District of Delaware for allegedly violating this invalid patent with their generic versions of Mirapex to keep them off the market;

(e) after three years of unnecessary litigation and a full trial, on the last day of the trial Boehringer filed a terminal disclaimer of the '812 Patent in favor of the '086 Patent, even though the '086 Patent has expired almost two years earlier. The Delaware District Court declared the '812 Patent invalid by clear and convincing evidence because of nonstatutory double patenting with respect to the '086 patent and the Court also found the terminal disclaimer to be ineffective and untimely and entered judgment against Boehringer;

(f) on June 26, 2008, despite knowing that their claims were meritless, appealing the Delaware District Court's decision finding that the '812 Patent was invalid;

(g) notwithstanding the Delaware District Court's ruling that the '812 Patent was invalid, filing an additional lawsuit in January 2009 in the United States District Court for the District of New Jersey, alleging that Mylan had infringed its invalid '812 Patent; and

(h) on June 10, 2009, filing a notice of appeal of the New Jersey District Court's Order in May 2009 granting Mylan's motion to dismiss the litigation.

5. After the Delaware District Court declared the '812 Patent invalid, Defendants conspired with Barr to further restrain trade and guarantee Defendants' unlawful monopoly power in the Mirapex market by entering into an agreement whereby Barr: (a) would not contest the appeal; and (b) would not launch a competing pramipexole product until January 2010. In return, Barr received, among other things, a valuable supply and co-promotion agreement to launch an authorized generic version of another drug, Aggrenox.

6. The combination of the litigation appeal and the conspiratorial agreement with Barr was designed to, and has had the effect of, further postponing the entry of a generic version of Mirapex into the market by delaying Barr's generic launch and, thus, its six-month exclusivity period before which other generic manufacturers (such as Mylan and Alembic) cannot enter.

7. As a result of the unlawful acts described herein, Defendants have: (a) unreasonably restrained, suppressed and eliminated competition in the Mirapex market; and (b) illegally maintained their monopoly in the Mirapex market. In return, this unlawful extension of market exclusivity has directly and proximately resulted in impeding generic competition, denying end-payors the benefits of free and unrestrained competition, and enabling Defendants to reap millions of dollars in ill-gotten monopoly profits at the end-payors' expense.

THE PARTIES

8. Plaintiff Vivian Branchofsky is a resident of Vermont. During the Class Period, she indirectly purchased Mirapex from Defendants and, thus, was injured by the illegal conduct alleged herein.

9. Defendant Boehringer Ingelheim International GmbH is a limited partnership organized and existing under the laws of Germany, having its principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

10. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

CO-CONSPIRATORS

11. Various other corporations, organizations, firms and individuals, not made defendants in this Complaint, including, *inter alia,* manufacturer Barr, participated as co-conspirators in the violations alleged herein, and performed acts in furtherance thereof.

JURISDICTION AND VENUE

12. This Court has diversity subject-matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, which amends 28 U.S.C. §1332 to add a new subsection (d) conferring federal jurisdiction over class actions where, as here, "any member of a class of Plaintiff is a citizen of a State different from any defendant" and the aggregated amount in controversy exceeds five million dollars ($5,000,000), exclusive of interest and costs. *See* 28 U.S.C. 1332(d)(2) and (6). This Court also has jurisdiction under 28 U.S.C. §1332(d) because "one or more members of the class is a citizen of a state within the

U.S. and one or more of the Defendants is a citizen or subject of a foreign state." The Court also has personal jurisdiction over the parties because Plaintiff submits to the jurisdiction of the Court and Defendants systematically and continually conduct business here and throughout the U.S., including marketing, advertising, and sales directed Vermont residents.

13. Venue is proper in this judicial district pursuant to 15 U.S.C. §22, and 28 U.S.C. §1391(b) because Defendants reside, transact business, are found, and/or have agents in this district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

RELEVANT MARKETS

14. To the extent applicable to the claims alleged herein, the relevant product market is the market for the manufacture and sale of Mirapex and its generic bioequivalents.

15. The relevant geographic market is the United States as a whole (for Counts I and IV), the applicable Indirect-Purchaser State (for Count II), and the applicable Unfair and Deceptive Trade Practices States (for Count III).

16. Defendants' market share in the relevant product and geographic markets was and continues to be 100%.

INTERSTATE TRADE AND COMMERCE

19. At all times relevant herein, Defendants manufactured, marketed and sold substantial amounts of Mirapex in a continuous and uninterrupted flow of interstate commerce.

20. Defendants utilized the United States mails and interstate and international telephone lines, as well as means of interstate and international travel, in order to effectuate their scheme to monopolize the market for Mirapex and its generic bioequivalents.

21. The illegal monopolization and attempted monopolization has, therefore, substantially affected interstate and foreign commerce.

FACTUAL ALLEGATIONS

The Hatch-Waxman Act and Competition between Branded Drugs and Generic Equivalents

22. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA" or "Act"), approval by the FDA is required before a company may begin selling a drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "branded" drug, must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period ("FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, codified at 21 U.S.C. § 355(j) ("Hatch-Waxman Act") and 35 U.S.C. § 271(e).

23. In addition to safety and efficacy information, NDA applicants must submit to the FDA a list of all patents purporting to cover drug for which FDA approval is being sought, or that claim a method of using that drug, for which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

24. Following NDA approval, the FDA lists any patents referenced in the NDA application in the Orange Book, where patents can be easily found and consulted by future FDA applicants.

25. Also following NDA approval, if a pioneer drug manufacturer obtains a new patent claiming the drug or its use, the manufacturer must supplement its NDA by submitting information on the new patent within 30 days of issuance. The new patent is then listed in a supplement to the Orange Book.

26. However, because the FDA must accept the new patent information as true and withhold subsequent drug applications whenever the patent holder presents a litigated dispute (no matter how baseless), the FDA is effectively powerless to stop unscrupulous patent holders which provide it with bogus information or file frivolous patent-infringement actions.

27. Generic drugs are those which the FDA has found to be bioequivalent to branded drugs (i.e., generic drugs have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs). Where a generic drug is completely bioequivalent, the FDA assigns the generic version an "AB" rating.

27. Invariably, generic drugs are priced significantly below the branded drugs to which they are bioequivalent (typically at least 30% lower). As additional generic competitors come to market, normally prices fall even further. As a result, unless the branded manufacturer lowers its prices to meet its competitors, generic manufacturers quickly capture market share from the brand-name manufacturer.

28. Exacerbating this effect are "automatic substation" laws which, in many states, require pharmacists to substitute AB-rated generics for branded drugs unless the physician has specifically indicated the prescription as "dispense as written" or some similar indication.

29. Therefore, the price competition created by generic drug manufacturers' entry into a market benefits all purchasers of a drug, who are able to achieve the same therapeutic benefits at substantially lower prices.

30. Due to these benefits, Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 in order to simplify and shorten the approval process for generic drugs. The Hatch-Waxman Amendments permit generic drug manufacturers to file an Abbreviated New Drug Application ("ANDA") that expedites the drug approval process.

31. Under the expedited ANDA process, if a generic drug is bioequivalent to the branded drug and receives an AB-rating, it will receive FDA approval without the need for clinical trials and the clearing of other regulatory hurdles required for pioneer drugs.

32. In an ANDA application, the filer must make one of four certifications to the FDA regarding the existence, or lack thereof, of patents purporting to cover the pioneer drug:

(a) that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

(b) that the patent for the pioneer drug has expired (a "Paragraph II Certification");

(c) that the patent for the pioneer drug will expire on a particular date, and that the filer does not seek to market its generic production before that date (a "Paragraph III Certification"); or

(d) that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification"). 21 U.S.C. §355(j)(2)(A)(vii).

32. In the event that an ANDA applicant seeks approval to market a generic version of a drug before the expiration of one or more patents listed in the Orange Book as covering that drug, the ANDA filer has no choice but to file a Paragraph IV Certification.

33. Upon receiving a Paragraph IV Certification, the purported patent holder is afforded 45 days in which to initiate a patent infringement suit against the ANDA application. If an action is brought with that period, the FDA cannot grant final approval of the ANDA

until the earlier of: (a) the expiration of the patent; (b) 30 months from the patent-holder's receipt of notification of the Paragraph IV Certification; or (c) the date on which a final judgment is entered in the patent infringement case holding that such patent is invalid, not infringed, or unenforceable.

34. Therefore, a branded-drug manufacturer can generally prevent entry of a generic drug for years simply by filing a patent infringement action even if the claims are completely meritless.

35. Where an ANDA applicant has satisfied all FDA regulatory requirements but the 30-month stay period has not expired, the FDA will grant tentative approval of the ANDA. This commonly signifies that the FDA would have granted a final approval but-for the stay period. Despite receiving tentative approval, however, the ANDA applicant cannot sell the generic product in the United States until it has received final approval from the FDA.

36. In addition to providing the expedited ANDA process for generic drugs, the Hatch-Waxman Amendments provide further incentive to generic manufacturers by providing the first ANDA filer for a generic version of a branded drug listed in the Orange Book a 180-day period of marketing exclusivity ("180-day exclusivity"). During that 180-day exclusivity period, no other generic manufacturers may enter the market.

37. The 180-day exclusivity period begins to run from the earlier of: (a) first date on which the ANDA product is commercially marketed; or (b) the date on which a court enters a final, non-appealable decision of invalidity or non-infringement regarding the listed patent. If the first ANDA filer does not launch its generic product within 75 days of one of these triggering events, the 180-day exclusivity period is forfeited.

Mirapex and Pramipexole Dihydrochloride

38. Mirapex is manufactured, marketed and sold by Boehringer throughout the entire United States. On July 1, 1997, Boehringer received approval from the FDA for Mirapex for the treatment of Parkinson's disease. In November 2006, the FDA further approved Mirapex for the treatment of moderate to severe Restless Leg Syndrome, also known as Wittmaack-Ekbom's Syndrome.

39. As of today, there are only three companies that have received either tentative or final approval from the FDA to market generic versions of Mirapex: Mylan (tentative approval received May 8, 2007); Barr (tentative approval received October 29, 2007 and final approval received February 19, 2009); and Alembic (tentative approval received July 20, 2009). But for Defendants' unlawful conduct, one or more of these manufacturers would have offered a generic product to compete with Mirapex.

40. The generic pramipexole products developed by Mylan, Barr and Alembic are AB-rated equivalents to Boehringer's branded Mirapex drug, which means they are considered bioequivalent substitutes and may be automatically substituted for Mirapex under certain state laws. As a result, the AB-rated equivalents are perfect competitive substitutes for Mirapex.

41. The generic pramipexole products would be priced substantially below the price Boehringer charges for Mirapex. Because Mirapex and its AB-rated equivalents are competitive substitutes and would be offered for a lower price, but for Defendants' misconduct, Plaintiffs and the other members of the Class would have paid substantially lower prices for Mirapex and its generic bioequivalents during the Class Period.

Defendants' Unlawful Scheme To Extend Their Mirapex Monopoly

42. Although several generic drug manufacturers sought approval to market generic versions of Mirapex in the United States, and although the products for which approval was sought did not infringe upon any valid patent, these generics have not come to market because of Defendants' unlawful and anticompetitive conduct. This conduct included: (a) obtaining the `812 Patent, which it knew or should have known was invalid because the patent claimed the same compound for which Boehringer had already received patent protection; (b) listing the '812 Patent in the Orange Book; (c) seeking a five-year extension of the invalid '812 Patent; (d) suing both Barr and Mylan for violations of this invalid patent; (e) after three years of unnecessary litigation and a full trial, on the last day of the trial Boehringer filed a terminal disclaimer of the ‘812 Patent in favor of the ‘086 Patent which the Delaware District Court found ineffective and untimely; (f) appealing the Delaware District Court's decision finding that the '812 Patent was invalid; (g) filing an additional lawsuit in the United States District Court for the District of New Jersey, alleging infringement on their invalid `812 Patent; and (h) appealing the New Jersey District Court's Order granting Mylan's motion to dismiss the litigation despite knowing that their claims were meritless.

43. In November 1987, Defendants applied for the '086 Patent, covering a method of treatment using tetrahydro-benzothiazoles, including the compound pramipexole.

44. While the '086 Patent application was pending, Defendants filed a second application for the '812 Patent, covering the pramipexole compound without reference to methods of treatment.

45. The '812 Patent, which applied for protection of a drug or method of treatment already covered by the '086 Patent, is a classic example of "double patenting." A patent obtained through double patenting is invalid and cannot be infringed.

46. On June 27, 1989, the U.S. Patent and Trademark Office ("PTO") approved the `086 Patent, and on December 12, 1989, the PTO approved the '812 Patent. Defendants applied for the '812 Patent despite the fact that it knew or should have known that it covered the same compound claimed in the '086 Patent and, thus, constituted invalid double-patenting.

47. Nonetheless, Defendants listed both patents in the Orange Book under the same specification and title, "Tetrahydro-Benzothiazoles, The Preparation Thereof and Their Use as Intermediate Products or as Pharmaceuticals."

48. Section 156 of the United States Patent Act ("Section 156") allows for the term of a patent to be extended where the commercial exploitation of the patented product is delayed by the applicant's seeking regulatory approval, such as by the FDA. The extension period lasts between the date the patent was granted and the date of marketing approval. Only one, unexpired patent per approved product may be extended.

49. On July 28, 1997, Defendants sought an extension under Section 156 for their invalid '812 Patent, which was to expire on December 12, 2006. The extension request was ultimately granted, extending the '812 Patent's expiration date until March 25, 2011. Defendants chose to seek a Section 156 extension of the invalid '812 Patent, as opposed to the original '086 Patent, in order to extend their monopoly as far into the future as possible.

50. On May 27, 2005, Barr filed an ANDA seeking FDA approval to market and sell a generic pramipexole 0.25 mg product that would have been bioequivalent to branded Mirapex.

51. On June 24, 2005, Barr amended its ANDA to cover other dosages of generic pramipexole products (0.125, 0.5, 1.0 and 1.5 mg) that would also have been bioequivalent to branded Mirapex.

52. On August 10, 2005 and September 12, 2005, Barr sent Defendants a letter notifying them that Barr had filed a Paragraph IV Certification asserting that their '812 Patent was either invalid or would not be infringed by Barr's generic product.

53. Defendants then sued Barr to enforce the '812 and the '086 Patents, even though they knew or should have known that their claims based on the '812 Patent were objectively groundless due to improper double-patenting. Defendants' motive for bringing this meritless infringement was to unlawfully extend their monopoly, thus enabling them to continue charging supra-competitive prices for Mirapex even after their '086 Patent would have expired.

54. As mandated by the Hatch-Waxman Amendments, Defendants' infringement suit, despite being completely meritless, automatically triggered a 30-month stay thwarting approval of generic versions of Mirapex despite being completely.

55. On August 26, 2005, a second generic manufacturer, Mylan, filed its own ANDA seeking approval to market and sell generic versions of Mirapex. Mylan informed Defendants that it had filed a Paragraph IV Certification via letter on October 26, 2005 and, within 45 days, was it too was sued by Defendants for patent infringement relating to the '812 Patent.

56. Defendants' filing of an infringement lawsuit against Mylan also triggered an automatic 30-month stay from the date it received Mylan's notice letter, preventing Mylan from receiving FDA approval and launching its generic versions of Mirapex.

57. On June 26, 2006, Defendants' original '086 Patent expired. Nonetheless, Defendants continued to pursue their patent infringement claims against Mylan and Barr to enforce their invalid '812 Patent, litigating all the way through a bench trial on the merits.

58. On March 11, 2008, at the conclusion of the bench trial and after subjecting the generic manufacturers to almost three years of meritless litigation, Defendants made the calculated decision to file a terminal disclaimer with the PTO. A terminal disclaimer is a binding statement made with the PTO when more than one patent has been obtained on the same invention, thus signifying that the later patent will expire at the same time as the earlier patent. When exercised properly, a terminal disclaimer can be used to cure double-patenting problems.

59. Although the proper filing of a terminal disclaimer ordinarily can cure the problems caused by double patenting, Defendants' disclaimer was improperly filed almost two years after the earlier-issued '086 Patent had expired and three years after they brought their sham patent infringement suits against Mylan and Barr.

The Delaware District Court Declares Boehringer's '812 Patent Invalid

60. On June 26, 2008, Judge Farnan of the U.S. District Court for the District of Delaware (the "Delaware District Court") issued an Opinion and Order in *Boehringer Ingelheim Ira*[q] *GmbH v. Barr Labs. Inc., et al.,* 562 F.Supp.2d 619 (D. Del. June 26, 2008). That Opinion and Order held that the '812 Patent was invalid, by clear and convincing evidence, due to nonstatutory double patenting.

61. In that Opinion and Order, the Delaware District Court found that it would be impossible to practice the claims in the '086 Patent without necessarily using or forming the compounds claimed in the '812 Patent. In so finding, the court further added, "allowing

Boehringer to secure a new patent on a compound which was itself specifically identified in the earlier method claims of the '086 patent is precisely the type of monopolistic conduct the doctrine of nonstatutory double patenting was designed to prevent." *Id.* at 639.

62. The Delaware District Court further concluded that the terminal disclaimer filed by Defendants was "ineffective" because a terminal disclaimer cannot overcome an obviousness-type double patenting problem when the earlier patent has already expired. *Id.* at 631-32. In so concluding, the court expressed concern about the timing of Defendants' terminal disclaimer stating that an "unreasonable delay" in filing can extend a monopoly, which is counter to the purpose of the terminal disclaimer provision, and because "extensive delay in filing a document which may ultimately moot a double patenting issue can have harsh effects on the judicial system as a whole resulting in gamesmanship during trial, and/or a waste of the Court's and the parties' resources." *Id.* at 632 n.8.

63. Even after the Delaware District Court declared the '812 Patent invalid, Defendants continued their elaborate scheme to unlawfully maintain monopoly power in the Mirapex market by delaying the entry of a final judgment and appealing the court's decision to the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit"). Tellingly, in their appeal to the Federal Circuit, Defendants do not challenge or even address the Delaware District Court's holding that the '812 Patent represented invalid double-patenting.

64. At oral argument in the Federal Circuit, two members of the panel noted that permitting a terminal disclaimer to a patent after its expiration would effectively allow patent

holders to "misuse the patent during the period before the disclaimer to discourage competition," and questioned Defendants' counsel whether that should be allowed.[1]

65. On January 26, 2009, notwithstanding the decision by the Delaware District Court or the pending appeal in the Federal Circuit, Defendants filed a new complaint against Mylan in New Jersey District Court for allegedly infringing their judicially-invalidated '812 Patent with respect to a 0.75 mg pramipexole product. The sole purpose of this baseless litigation was to further delay entry of a generic 0.75 mg pramipexole product, thus enabling Defendants to squeeze even more unlawful monopoly profits out of end-consumers.

66. Not surprisingly, following oral argument, the New Jersey District Court granted Mylan's motion to dismiss from the bench in May 2009. Again not surprisingly, Defendants filed another meritless notice of appeal to the Federal Circuit on June 10, 2009.

Boehringer Conspires With A Potential Competitor To Guarantee Extension Of Its Unlawful Monopoly

67. At the same time it elected to appeal the decision of the Delaware District Court, Defendants simultaneously reached a settlement with Barr, the first-filer of an ANDA application for generic Mirapex.

68. Although the full terms of the agreement have not been made public, it has been reported that Barr agreed not to contest Defendants' appeal and not to launch a competing pramipexole product until January 2010. In return, Barr received a supply and co-promotion agreement to launch an authorized generic version of a totally different drug, Aggrenox, 18 months before Boehringer's last patent for that drug is set to expire.

[1] Oral argument, *available at* http://oralarguments.cafc.uscourts.gov/mp3/2009-1032.mp3.

69. Barr also has not relinquished its rights to the 180-day exclusivity period as first ANDA filer for generic Mirapex. As a result, other potential generic manufacturers of pramipexole products have been wrongfully prevented from launching their generics until either 75 days from the affirmance of the Delaware District Court's decision by the Federal Circuit or, if Barr launches its pramipexole products within that period, 180 days after Barr's commercial launch.

70. Thus, the conspiracy between Defendants and Barr—the first applicant to file an ANDA for generic Mirapex—has succeeded in ensuring that generic competition in the Mirapex market will continue to be unlawfully restrained, and Defendants will continue to receive ill-gotten monopoly profits at the expense of Plaintiffs and the other members of the Class.

Damage And Harm Caused By Defendants' Unlawful Conduct

71. Defendants' conduct had the purpose and effect of eliminating competition and wrongfully extending their monopoly power, thus enabling Defendants to continue to charge supra-competitive prices for Mirapex.

72. Defendants have engaged in monopolistic practices and entered into a conspiratorial agreement concerning Mirapex in order to avoid the loss in market share and revenues that would inevitably result from the introduction of generic competition in the Mirapex market.

73. But for Defendants' misconduct, other manufacturers would have launched generic pramipexole products as early as June 26, 2006, the date Boehringer's '086 Patent expired. As a result, Plaintiffs and the other members of the Class have been denied the

opportunity to purchase less expensive generics equivalent to Mirapex and will continue to pay supra-competitive prices for pramipexole products.

74. If a generic competitor had been able to enter the relevant market and compete with Defendants, end-consumers such as Plaintiffs would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for Mirapex and pramipexole products. As noted above, pharmacists generally are permitted, and in many instances are required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, third-party payors of prescription drugs (e.g., managed care plans) encourage or insist on the use of generic drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year

75. By preventing generic competitors from entering the market, Defendants injured Plaintiffs and the other Class members in their business or property by causing them to pay more for Mirapex and pramipexole products than they otherwise would have paid. Thus, Defendants' unlawful conduct deprived Plaintiffs and other end-consumers of the benefits of competition that the antitrust laws and applicable state consumer protection laws were designed to preserve.

76. Defendants' unlawful conduct is continuing and, without the intervention of the Court, end-consumers face continuing damage and injury from the continued exclusion of generic pramipexole products from the market.

CLASS-ACTION ALLEGATIONS

77. Plaintiff brings this class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure on behalf of himself and the following class members:

Injunctive-Relief Class
All persons and entities in the United States who, at any time from June 26, 2006 until present (or whatever time in the future Defendants cease their anticompetitive behavior, generics enter the relevant market, and a competitive pricing prevails) indirectly purchased Mirapex in the United States other than for re-sale.

Excluded from the Class are the Defendants, their subsidiaries and affiliates, and government entities. For purposes of the Class definition, persons and entities "purchased" Mirapex if they paid some or all of the purchase price.

Plaintiff also brings this class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure on behalf of himself and the following class members:

Money-Damages Class
All persons and entities in Vermont who, at any time from June 26, 2006 until present (or whatever time in the future Defendants cease their anticompetitive behavior, generics enter the relevant market, and a competitive pricing prevails) indirectly purchased Mirapex in the Vermont other than for re-sale.

Excluded from the Class are the Defendants, their subsidiaries and affiliates, and government entities. For purposes of the Class definition, persons and entities "purchased" Mirapex if they paid some or all of the purchase price.

78. Plaintiff believes that there are thousands of members in the above-described Class; their exact number and identities being currently unknown to Plaintiffs, but known to Defendants and/or ascertainable from appropriate discovery.

79. Among the questions of law and fact common to the Class are:

(a) whether Defendants have unlawfully monopolized or attempted to monopolize the market for Mirapex;

(b) whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Mirapex;

(c) whether Defendants, through their monopolization and/or attempted monopolization, have caused the prices of Mirapex to be maintained at supra-competitive levels;

(d) whether Defendants' patent infringement lawsuits against companies seeking to manufacture, market and sell generic Mirapex constitute unlawful conduct;

(e) whether the agreement between Defendants and Barr which has prevented Barr, and thus other generic manufacturers, from entering the Mirapex market constitutes an unlawful contract, combination or conspiracy in restraint of trade;

(f) whether the Class suffered and continues to suffer antitrust injury; and

(g) whether Defendants were and continue to be unjustly enriched to the detriment of the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

80. Plaintiffs' claims are typical of the Classes because it and all members of the Classes were injured and continue to be injured in the same manner by defendants' unlawful, anticompetitive and inequitable methods, acts and practices, and wrongful conduct in the conspiracies complained of herein (i.e., they have paid supra-competitive and artificially high prices for Mirapex and will continue to be forced to do so until the markets for Mirapex are competitive).

81. Plaintiff will fully and adequately protect the interests of all members of the Class. Plaintiff has retained counsel experienced in antitrust class action litigation. Plaintiff has no interests which are adverse to, or in conflict with, other members of the Class.

82. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

83. The Class is readily definable and prosecution as a class action will eliminate the possibility of duplicative litigation, while also providing redress for claims which would otherwise be too small to support the expense of individual, complex litigation.

84. Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Class as a whole.

COUNT I
(Applicable to the Injunctive-Relief Class)
VIOLATION OF THE CLAYTON ACT

85. Plaintiff incorporates by reference the preceding allegations.

86. To the extent applicable to this and other claims alleged in this Complaint, the relevant product market is the market for the manufacture and sale of Mirapex and its generic bioequivalents. The relevant geographic market is the United States as a whole. Defendants' market share in the relevant product and geographic markets has been and continues to be 100%.

87. Defendants knowingly and willfully engaged in a course of conduct designed to unlawfully extend their monopoly power. This course of conduct included, *inter alia*:

(a) listing the '812 Patent in the Orange Book to raise entry barriers;

(b) knowingly seeking a five-year extension of the invalid '812 Patent;

(c) suing both Barr and Mylan in the United States District Court for the District of Delaware for allegedly violating this invalid patent with their generic versions of Mirapex to keep them off the market;

(d) on June 26, 2008, despite knowing that its claims are meritless, appealing the Delaware District Court's decision finding that the '812 Patent was invalid;

(e) notwithstanding the Delaware District Court's ruling that the '812

Patent was invalid, filing an additional lawsuit in January 2009 in the United States District Court for the District of New Jersey, alleging that Mylan had infringed their invalid '812 Patent; and

(f) after three years of litigation and a full trial, Boehringer filed a terminal disclaimer of the '812 Patent in favor of the expired '086 Patent;

(g) on June 10, 2009, filing a notice of appeal of the New Jersey District Court's Order in May 2009 granting Mylan's motion to dismiss the litigation.

88. Defendants' filing and defense of obviously invalid patents violates Section 2 of the Sherman Act. Defendants filed and defended subsequent patents with knowledge that they were invalid due to nonstatutory double patenting. The intended effect of these objectively baseless actions was to delay the introduction of generic formulations of Mirapex into the market.

89. Defendants' agreement with Barr to prevent all generic versions of Mirapex from entering the market violated Section 1 of the Sherman Act. The agreement was designed to, and has the effect of, restraining competition in the market by virtue of a contract, combination or conspiracy amongst horizontal competitors.

90. Defendants' filing and defense of obviously invalid patents are part of a policy of Defendants, sometimes euphemistically referred to in the industry as "life-cycle management," to file patents without regard to their merits and for the purpose of injuring competitors. Indeed, Defendants have acknowledged that they seek to be "clever" with their patents in order to defend their "life-cycle" through on-going programs at Defendants' businesses.

91. During the Class Period, Defendants possessed monopoly power in the relevant market. Defendants intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. While obtaining

and possessing their unlawful monopoly power over the market for Mirapex, Defendants set, maintained and raised the price of Mirapex to artificially high and/or supra-competitive levels.

92. Plaintiffs and the other Class members have been injured in their business or property by reason of Defendants' antitrust violations. Their injury consists of paying higher prices for Mirapex and pramipexole purchases than they would have paid in the absence of such violations. This is the sort of injury that antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

93. Plaintiffs and the members of the Class are likely to purchase Mirapex and pramipexole again in the future. Therefore, injunctive relief is appropriate under 15 U.S.C. 26.

94. Plaintiffs and the Class seek injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the Defendants' unlawful conduct, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT II
(Applicable to the Money-Damages Class)
VIOLATION OF VERMONT STATUTORY LAW

95. Plaintiffs incorporate by reference the preceding allegations.

96. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and the members of the Class were deprived of the opportunity to purchase a generic Mirapex.

97. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Vt. Stat. §2451, *et. seq.*

98. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Mirapex than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT III
(Applicable to the Money-Damages Class)
UNJUST ENRICHMENT

99. Plaintiff incorporates by reference the preceding allegations.

100. Defendants have benefited from their unlawful acts through overpayments for Mirapex and pramipexole product by Plaintiff and the Class members and the increased profits resulting from such overpayments. It would be inequitable for Defendants to be permitted to retain the benefit of these overpayments, which were conferred by Plaintiff and other Class members and retained by Defendants.

101. Plaintiff and members of the Class are entitled to the establishment of a constructive trust consisting of the benefit to Defendants of such overpayments, from which Plaintiff and the Class members may make claims on a *pro-rata* basis for restitution.

PRAYER FOR RELIEF

A. That this Court determine that this action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure and certify either or both classes;

B. With respect to the Injunctive-Relief Class, that this Court rule that Defendants' conspiracy violated the Sherman Act and that injunctive relief under the Clayton Act is appropriate;

C. With respect to the Money-Damages Class, that this Court rule that Defendants' conspiracy violated Vermont law and that compensatory damages, including treble damages, or full consideration trebled, are appropriate;

D. With respect to the Money-Damages Class, that this Court determine that Defendants were unjustly enriched;

E. That this Court award Plaintiff post-judgment interest, his costs, and reasonable attorneys' fees; and

F. That this Court order any other relief as it deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury as to all issues of right to a jury.

Dated: October 9, 2009

Respectfully submitted,

By: s/ Alfred G. Yates, Jr.

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